DEC 1 2 2005

510(k) Summary of Safety and Effectiveness

Orthofix Titanium Nailing System

510(k) K053261

1. General Information:

Proprietary Name	Orthofix Titanium Nailing System
Common Name	Intramedullary Nail
Regulatory Class	II
Device Classification	87HSB (21 CFR 888.3020) 87JDS (21 CFR 888.3030)
Submitter	R. Sheridan Consulting, LLC 632 Dundee Drive Wilmington N.C. 28405 USA
Registration number	9680825
Contact Person	Rolando Stanghellini Via delle Nazioni 9 37012 Bussolengo (VR) Italy
Summary Preparation Date	November 15th, 2005

2. Description

The Orthofix Titanium Nailing system consists of intramedullary nails, locking screws and additional implantable components made of a titanium alloy. The nails included in the system are designed to treat several types of fractures of the humerus, femur and tibia. Nails come in various shapes and diameters and can be cannulated, straight, curved or with a bend.

All nails are locked with various types of locking screws, specifically designed for the type of nail and fracture treated. Nails might have several locking options (varying in number and direction of fixation points and type of screws to be inserted), thus allowing a customized fragment adapted approach. Accessories include end caps, nuts and washers.

Instrumentation is available for the insertion and removal of nails, screws and end caps.

3. Intended Use

Each nail within the Orthofix Titanium Nailing System is intended for insertion into the medullary canal of a specific long bone – humerus, femur and tibia – for the alignment, stabilization and fixation of various types of fractures or deformities caused by trauma or disease. These include: traumatic fractures, re-fractures, non-union, reconstruction, malunion, malalignment, pathological fractures and impending pathological fractures.

4. Substantial equivalence

Documentation is provided which demonstrates the Orthofix Titanium Nailing System to be substantially equivalent to other legally marketed devices. The nails included in the Orthofix Titanium Nailing system and the predicate devices are all intramedullary fracture fixation systems as defined in 21 CFR 888.3020, furthermore, the size, shape and materials for the subject devices are comparable to the predicate devices.

5. Conclusion

Based upon the similarities in design, materials and intended uses of the Orthofix Titanium Nailing System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2005

Orthofix SRL
c/o Candace F. Cederman
Sheridan Consulting, LLC
632 Dundee Drive
Wilmington, NC 28405

Re: K053261
Trade/Device Name: Orthofix Titanium Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB, JDS
Dated: November 21, 2005
Received: November 22, 2005

Dear Ms. Cederman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053261

Device Name: Orthofix Titanium Nailing System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053261